

### REMARKS

The September 4, 2007, Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the September 4, 2007, Official Action. Therefore, the initial due date for response was December 4, 2007. This paper is accompanied by a petition for a two (2) month extension of time and the requisite fee and is being filed within the two month extension period.

Applicants note that claims 1, 4-6, 9, 11, 13, 16-18, 20-22, 27-32 are subject to examination and claims 7-8, 14-15 and 23-26 are withdrawn because they are drawn to unelected subject matter. Furthermore, it is noted that the restriction requirement between Groups I and Groups III and IV, mailed December 18, 2006, has been withdrawn. The Examiner has also indicated that claims 1, 4-6, 11, 13, 16-18, 27 and 29 are allowed.

As a preliminary matter, the Examiner has withdrawn the previous rejection of claims 1, and 4-6 under 35 U.S.C. §112, first paragraph, for allegedly containing new matter. Also, the rejection under 35 U.S.C. §102(b) to claim 1 as allegedly being anticipated by Houghton et al., Seipp et al., or Kato et al. have been withdrawn, and the §102(b) rejection of claims 1, and 4-5 as allegedly being anticipated by Sasagawa et al. and Wu et al. have been withdrawn.

Turning to the substantive aspects of the September 4, 2007, Official Action, at page 2, the Examiner has rejected claims 9, 20-22, 28, and 30-32, under 35 U.S.C. §112, second

paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

At page 4 of the Official Action, the Examiner has rejected claim 20 under 35 U.S.C. §102(b) as allegedly anticipated by Kato et al. (BBRC 206:863-869 (1995)).

The Examiner has also rejected claims 20-22 under 35 U.S.C. §102(b) as allegedly being anticipated by Mizumo et al. (Gastroenterol. 109:1933-1940 (1995)).

Lastly, claims 20-22 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent 6,096,541 to Houghton et al.

The foregoing rejections constitute all of the grounds set forth in the September 4, 2007, Official Action for refusing the present application. In light of the amendments to the claims and the following remarks, each of the above-noted rejections under 35 U.S.C. §112, second paragraph, and §102(b) are respectfully traversed. Applicants submit that the claims, as presently amended, are in condition for allowance.

**CLAIMS 9, 20-22, 28, AND 30-32, AS AMENDED, SATISFY THE  
REQUIREMENTS OF 35 U.S.C. §112, SECOND PARAGRAPH**

The Examiner has rejected claims 9, 20-22, 28, and 30-32, asserting that they are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The relevant inquiry in determining whether a given claim satisfies the requirements of 35 U.S.C. §112, second paragraph, is whether the claim sets out and circumscribes a particular area with a reasonable degree of precision and particularity such that the metes and bounds of the claimed invention are reasonably clear. In re Moore, 169 U.S.P.Q. 236 (CCPA 1971).

Applicants respectfully submit that with respect to amended independent claim 20 and the dependent claims of the present application, such inquiry must be answered in the affirmative.

At page 3 of the Official Action, the Examiner rejected claim 20 asserting that the recitation "the RNA from a second cell line which comprises and HCV genome" is confusing since it is unclear what RNA from the second cell line is necessary to make the claimed invention. In response, Applicants have amended claim 20 in keeping with the Examiner's helpful suggestion (i.e., wherein the cell line comprises "genomic HCV RNA and has been transfected with total RNA from a second HCV-replicating human cell line."). Applicants submit that this amendment clarifies the meaning of the claim and renders the rejection moot.

In light of the foregoing remarks and claim amendment, Applicants respectfully submit that the metes and bounds of the claims, as amended, are clear to the skilled person. Accordingly, it is requested that the above-mentioned rejection under 35 U.S.C. §112, second paragraph be withdrawn.

**CLAIMS 20-22, AS AMENDED, ARE NOT ANTICIPATED BY THE REFERENCES  
CITED BY THE EXAMINER**

The Examiner has rejected claims 20-22 under 35 U.S.C. §102(b) as allegedly being anticipated by several references which are discussed in turn below.

On page 4, point 6 of the Official Action, claim 20 has been rejected under §102(b) as allegedly being anticipated by Kato et al. (1995). Newly amended claim 20 is drawn to a human, non-hepatic cell line comprising genomic HCV RNA which has been transfected with total RNA from a second HCV-replicating human cell line. Kato et al. allegedly teach that MT-2 cells are a cell line which supports HCV replication, and furthermore, MT-2

cells comprise mRNA and tRNA in common with Huh-7 cells.

Applicants respectfully disagree with the Examiner's position and submit that Kato et al. fail to disclose a cell line identical to that of Applicants. It is a well-settled premise in patent law that in order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

As mentioned above in regard to the indefiniteness rejection, Applicants have amended claim 20 to recite a cell line comprising genomic HCV RNA which has been transfected with total RNA from a second HCV-replicating human cell line. Kato et al. fail to teach a cell line with transfected with rRNA and HCV genomic RNA from a second HCV-replicating cell line. It is evident from the above that the instant rejection of claim 20 is untenable as Kato et al. fail to teach each and every element of claim 20. Withdrawal of the rejection is respectfully requested.

On page 4, point 7 of the Official Action, the Examiner has rejected claims 20-22 under §102(b) as allegedly anticipated by Mizumo et al. (1995). Mizumo et al. describe HeLa cells as a cell line supporting HCV replication, and further that HeLa cells comprise mRNA and tRNA in common with Huh-7 cells. Claims 21-22 depend from amended independent claim 20 which is discussed above.

Applicants disagree with the Examiner's position regarding Mizumo et al. for at least the reasons stated above regarding Kato et al., and reiterate that the references are silent and fail to describe a cell line transfected with total RNA from a HCV-replicating cell line. Accordingly, Applicants submit that claims 20-22 are patentable over the cited references and request withdrawal of this §102 rejection based on Mizumo et al.

Claims 20-22 have also been rejected on page 4 of the Official Action under §102(b) as allegedly being anticipated by Houghton et al. (2000). Houghton et al. indicate that HeLa cells support HCV replication, and further indicated that HeLa cells comprise mRNA and tRNA in common with Huh-7 cells. Again, Applicants submit that amended claim 20 relates to a cell line comprising genomic HCV RNA generated by transfecting total RNA from a HCV-replicating human cell line. Claim 20 necessarily includes genomic and rRNA, while Houghton et al., as well as the other references cited, fail to anticipate this independent claim.

In sum, Applicants respectfully submit that the present claims are novel over the references cited by the Examiner, and Applicants respectfully submit that the rejections of claims 20-22 are inappropriate and request their withdrawal.

#### **CONCLUSION**

It is respectfully requested that the amendments presented herewith be entered in this application. These amendments and remarks are believed to clearly place the pending claims in condition for allowance. Therefore, it is respectfully urged that the rejections set forth in the September 4, 2007, Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the

allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned at the phone number give below.

Respectfully submitted,  
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